

BRIVANT MEDICAL ENGINEERING	Brivant Guidewire Premarket Notification 510(k)
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510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

(1) Submitter's Name / Contact Person: Brivant Limited,
4 Westlink Commercial Park,
Oranmore,
Galway,
Ireland

JUN - 7 2006

Contact Person: Tomas Furey,
Vice President Regulatory Affairs
Tel: (011) 35391 788960
Fax: (011) 35391 788961

(2) Summary Preparation Date: February 17, 2006

(3) Device Name and Classification:

Trade Name: Brivant Guidewire
Common Name: Guidewire
Classification Name: Catheter, Guidewire
Device Classification: Class II, 21 CFR §870.1330

(4) Identification of Predicate Devices:

#	Manufacturer	Device	510(k) No.
1	Invatec Innovative Technologies	SKIPPER and SKIPPER RACE Guidewires	K050756
2	Biosphere Medical Inc.	Segway GT SEG1812	K011287 K032129

This summary is provided in compliance with section 513(i)(3)(a) of the Act and summarizes the safety and effectiveness information contained in this premarket notification submission.

(5) Description of the Device:

The Brivant Guidewire is a disposable medical device designed for single use only. It consists of a 0.014" or 0.018" diameter stainless steel core wire, one end of which is reduced in diameter over the distal coil segment in a progressive fashion. The Brivant Guidewire is produced in lengths of 175, 195 and 300cm and is available in either silicone or hydrophilic coatings. The profile of the reduced section is varied to provide a range of products of mixed stiffness.

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(6) Statement of Intended Use:

The Brivant guide wires are intended for use in the coronary and peripheral vasculature

(7) Predicate Device Comparison:

Brivant Guidewires are substantially equivalent to the SKIPPER and SKIPPER RACE guidewires, Invatec Innovative Technologies (K050756 cleared for marketing on May 5, 2005) and Segway GT SEG1812 Guidewire, Biosphere Medical Inc.(K011287, K032129) in terms of the indications for use, functional effectiveness, technological characteristics, materials and principles of operation. Brivant Guidewires shall be manufactured according to specified process controls and in compliance with an ISO 9001:2000/ISO 13485:2003/FDA QSR 820 Quality Assurance Program. The devices will undergo packaging and sterilization procedures in compliance with internationally recognized standards.

(8) Summary of Testing:

Performance testing involving the following testing has been completed tensile strength, torque strength, torque response, coating performance, radiopacity, packaging qualification (including accelerated aging), sterilization validation, tip flexibility, catheter compatibility testing and biocompatibility testing in compliance with ISO 10993-1 has been successfully completed. The successful tests demonstrated the Brivant Guidewires consistently performed within their design parameters, are safe and effective and perform as well as the predicate devices.

(9) Statement of Equivalence:

Brivant Guidewires are substantially equivalent to the SKIPPER and SKIPPER RACE guidewires (K050756) and Segway GT SEG1812 Guidewire (K011287, K032129) in intended use, materials, principle of operation, technological characteristics and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2006

Brivant Medical Engineering
c/o Mr. Tomas Furey
Vice President, Regulatory Affairs
4 Westlink Commercial Park
Oranmore, Galway, Ireland

Re: K060551

Brivant Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (Two)
Product Code: DQX
Dated: May 15, 2006
Received: May 18, 2006

Dear Mr. Furey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K060551

Device Name: **Brivant Guidewire**

Indications for Use: Brivant guidewires are intended for use in the coronary and peripheral vasculature.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Vachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060551